IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, *Plaintiff*, v. SANDOZ, INC., et al. *Defendants*.	§ § § § § § § § §	CASE NO. 2:12-CV-207-JRG **(LEAD CASE)**
ALLERGAN SALES, LLC, *Plaintiff*, v. SANDOZ, INC., et al. *Defendants*.	§ § § § § § § § § §	CASE NO. 2:15-CV-347-JRG

OPINION AND FINAL JUDGMENT

This case came before the Court for a bench trial beginning on October 25, 2016. The trial was completed on October 27, 2016. The issues having been duly tried, and the Court having issued its Findings of Fact and Conclusions of Law, separately but concurrently herewith, the Court hereby issues this Opinion and Final Judgment.

I. BACKGROUND

The Court provides the following overview of the proceedings to provide context to the claims and defenses presently asserted.

A. Procedural History

Allergan Sales, LLC ("Allergan") is the holder of approved New Drug Application ("NDA") No. 21-398 for the drug Combigan®. (Dkt. No. 311 at 5.) Combigan® is a fixed combination ophthalmic solution consisting of 0.2% brimonidine and 0.5% timolol designed to lower intraocular pressure in patients with glaucoma and ocular hypertension. (Dkt. No. 277 at 3; Dkt. No. 311 at 5.) Allergan has at least six patents alleged to cover Combigan® and its administration: U.S. Patent Nos. 7,030,149 ("the '149 patent"); 7,320,976 ("the '976 patent"); 7,642,258 ("the '258 patent"); 8,133,890 ("the '890 patent"); 8,354,409 ("the '409 patent"); and 8,748,425 ("the '425 patent"). (Dkt. No. 311 at 5.) Each of these patents is listed in the FDA-Approved Drug Products with Therapeutic Equivalence Evaluations database, commonly referred to as the "Orange Book." (*Id.*) Allergan is also the owner of U.S. Patent. No. 7,323,463 ("the '463 patent"), which is also listed in the Orange Book, however Allergan has requested that the '463 patent be de-listed. (*Id.*)

1. *Allergan I*

In 2009, Allergan received three Paragraph IV letters from Sandoz, Inc. ("Sandoz") regarding the '149, '976, '463, and '258 patents. *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974, 985 (E.D. Tex. 2011) ("*Allergan I*"). These letters indicated that Sandoz had submitted Abbreviated New Drug Application ("ANDA") No. 91-087 for the purpose of obtaining approval to commercially manufacture, use, offer for sale, or sell a generic version of Combigan prior to the expiration of the '149, '976, '463, and '258 patents. *Id.* After receiving the letters, Allergan filed suit against Sandoz for infringement of the '149, '463, '976, and '258 patents. *Id.* Sandoz raised affirmative defenses and counterclaims of invalidity of the patents-in-suit. (*See* C.A. No. 2:09-cv-97, Dkt. Nos. 35, 83). Thereafter, Sandoz moved for summary judgment of

non-infringement of claims 1 through 3 of the '149 patent, which the Court granted. *Allergan I*, 818 F. Supp. 2d at 982. Shortly before trial, Sandoz filed a stipulation that its ANDA met all of the limitations of claim 4 of the '149 patent, claim 1 of the '976 patent, claims 1–6 of the '463 patent, and claims 1–9 of the '258 patent. (C.A. No. 2:09-cv-97, Dkt. No. 234.) The case proceeded to a bench trial on the issue of invalidity of the remaining asserted claims. Based on the stipulations, the Court found the claims to be infringed. The Court also found the claims to be not invalid, based on the evidence presented at trial. *Allergan I*, 818 F. Supp. 2d at 1031. The Court subsequently enjoined Sandoz from making, using, offering to sell, or selling the products described in the ANDA within the United States until after the latest of the expiration dates of the '149, '976, '463, and '258 patents. (C.A. No. 2:09-cv-97, Dkt. No. 260.)

Allergan and Sandoz both appealed the Court's ruling to the Federal Circuit. *See Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286 (Fed. Cir. 2013). On appeal, the Federal Circuit affirmed-in-part and reversed-in-part, finding that the asserted claims of the '463 patent were invalid as obvious. *Id.* at 1288. However, the Federal Circuit affirmed this Court's holding that claim 4 of the '149 patent was not invalid, reasoning that Sandoz failed to present clear and convincing evidence that the "no loss of efficacy" limitation of such claim would have been obvious. *Id.* at 1288, 1294. The Federal Circuit declined to address the claims of the '258 and '976 patents, explaining that "[t]he '258, '976, and '149 patents each expire on April 19, 2022. Because we conclude that claim 4 of the '149 patent is not invalid, the Appellants will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the '258 and '976 patents." *Id.* at 1294 n.2.

2. *Allergan II*

In March of 2012, while *Allergan I* was still pending in this Court, the '890 patent issued. (Dkt. No. 1 ¶ 23.) Shortly thereafter, Allergan filed suit against Sandoz alleging that Sandoz's ANDA No. 91-087 infringed the '890 patent. (Dkt. No. 1) ("*Allergan II*"). On March 15, 2013, Sandoz amended its answers to add counterclaims for non-infringement and invalidity of the later-issued '409 patent, as well as non-infringement and invalidity of the '890 patent. (Dkt. No. 311 p. 6–7.) *Allergan II* was ultimately consolidated with *Allergan III* to form the present action. (Dkt. No. 220.)

3. *Allergan III*

While *Allergan I* was on appeal, Sandoz modified its ANDA No. 91-087 to remove the indicated use of glaucoma from its label by removing the words "glaucoma or" from a label that originally indicated use of the product "for the reduction of elevated intraocular pressure ("IOP") in patients with glaucoma or ocular hypertension." (Dkt. No. 287 p. 7–8.) As a result, Sandoz now only seeks approval of its product in patients with ocular hypertension. (*Id.*) After Sandoz modified its ANDA, it filed a Rule 60(b)(5) motion to modify the injunction the Court issued in *Allergan I* to permit Sandoz to make its proposed ANDA product. (C.A. No. 2:09-cv-97, Dkt. 280.) This Court denied Sandoz's Rule 60(b)(5) motion, (C.A. No. 2:09-cv-97, Dkt. No. 308), and the Federal Circuit affirmed. *Allergan, Inc. v. Sandoz, Inc.*, 587 Fed. App'x 657 (Fed. Cir. 2014).

On January 23, 2015, Sandoz sent a second Paragraph IV letter to Allergan, which notified Allergan of Sandoz's modified ANDA. (2:15-cv-347, Dkt. No. 1 ¶ 33–34.) Following receipt of the Paragraph IV letter, Allergan again filed suit against Sandoz, this time for infringement of the '149, '976, '258, '425 patents. (2:15-cv-347, Dkt. No. 1) ("*Allergan III*"). As

noted above, the Court then consolidated *Allergan II* and *Allergan III*. (Dkt. No. 220.) It was this consolidated action which proceeded to trial before the Court on October 25, 2016 on the '149, '976, and '425 patents (collectively "the patents-in-suit").

B. Sandoz's Modified ANDA and the '425 Patent

The Court issues this opinion along with its Final Judgment due, in part, to its concerns with Sandoz's pre-litigation conduct which led to the institution of the present lawsuit. Specifically, Sandoz's repeated efforts to relitigate a case which it lost on the merits in 2011 are cause for concern. The genesis of this relitigation strategy lies with Sandoz's amended ANDA No. 91-087. Whereas previously Sandoz's ANDA was indicated for usage in patients with "glaucoma or ocular hypertension," its amended ANDA was indicated solely for use in patients with "ocular hypertension." In other words, it omitted the words "glaucoma or" from its proposed label. It is undisputed that the drug to be sold is chemically identical to Combigan®. Said another way, the removal of these two words constituted the entirety of Sandoz's modifications to its ANDA.

After making this amendment, Sandoz undertook a series of calculated litigation-based actions which appear to the Court to have pushed the envelope of propriety for their strategic gain. First, Sandoz moved under Rule 60(b)(5) to modify the injunction issued in *Allergan I* in light of its amended ANDA. Sandoz argued, in part, that because its amended ANDA carved out use of the product in patients with glaucoma, its product would no longer infringe claim 4 of the '149 patent. (C.A. No. 2:09-cv-98, Dkt. No. 285 at 11–12.) In support of its argument, Sandoz highlighted the fact that the FDA had "informed Sandoz that its carve-out amendment was acceptable." (C.A. No. 2:09-cv-97, Dkt. No. 300 at 1.) The Court denied Sandoz's Rule 60(b)(5) motion on the grounds that it was simply seeking to relitigate its case and "obtain another chance

at non-infringement via the modified ANDA." (C.A. No. 2:09-cv-97, Dkt. No. 308 at 6–7.) Accordingly, the Court found that the motion sought improper relief. After losing on its Rule 60(b)(5) motion, Sandoz sent a modified Paragraph IV letter to Allergan, representing that it had amended its ANDA to "carve out" the indicated use of the drug in patients with glaucoma. (C.A. No. 2:15-cv-347, Dkt. No. 1 ¶ 33–34.) Allergan responded to this letter by filing another lawsuit, this time for infringement of the '149, '976, '258, '425 patents. (C.A. No. 2:15-cv-347, Dkt. No. 1.) After precipitating a second lawsuit, Sandoz faced two hurdles obstructing its path to successful relitigation. Sandoz's first hurdle in this suit was overcoming an unfavorable claim construction (to which it stipulated) in *Allergan I*. As discussed in greater detail below and in this Court's Findings of Fact and Conclusions of Law, the *Allergan I* claim construction is fundamentally at odds with the arguments Sandoz advanced at the trial in the present suit. To avoid this problem, Sandoz argued for a new claim construction, which was different than that of *Allergan I*. After obtaining a different claim construction, Sandoz faced its second hurdle: issue and claim preclusion. At that juncture, the Court found that Allergan was not legally precluded from making its amendment and relitigating with Allergan. As detailed in its order denying Allergan's motion for summary judgment (Dkt. No. 314), the Court found that the identical issues had not previously been litigated (given the stipulations between the parties). At this point, the door to relitigation had been opened.

Sandoz's relitigation strategy is clear. Sandoz stipulated to infringement in *Allergan I*, but then realized it relinquished plausible non-infringement arguments by doing so. Sandoz regretted its stipulation, and sought to relitigate infringement of Allergan's patents. After litigator's remorse set in, the key to Sandoz's relitigation strategy was amending its ANDA to technically say it covered a new product. At this juncture, the Court makes clear that Sandoz's motivation to

amend its ANDA, and the act of doing so, is not inherently problematic. Indeed, Sandoz was not legally precluded from making this amendment and pursuing relitigation. However, the non-infringement arguments Sandoz advanced at trial in the present suit persuade the Court that its amendment was purely a means to an end. For example, at trial Sandoz did not argue that the amendment to its ANDA actually designed around Allergan's patents by bringing what had previously been an infringing product outside the scope of the asserted claims. Rather, the arguments it presented had absolutely no relation to the amendment it made to its ANDA. That is to say, it could have made these identical non-infringement arguments in *Allergan I*, given that they apply equally to its original ANDA and its amended ANDA. Since the amended ANDA did not give rise to any new arguments, it was less a design around Allergan's patents and more a hypertechnical, if not illegal, end run around the injunction stemming from *Allergan I*. The only utility of Sandoz's amended ANDA was as a key to open the door to arguments that Sandoz regretted giving up in *Allergan I*.

In spite of the above, the Court finds some of Sandoz's arguments persuasive. As explained below, the Court concludes that Sandoz's proposed product described in its amended ANDA does not infringe the '149 patent or the '976 patent. However, the Court finds that Sandoz's non-infringement arguments with respect to the '425 patent fall short, and that Allergan has carried its burden to establish infringement of the '425 patent. With this background in mind, the Court observes that such clear efforts to creatively bypass the principles of finality and fairness underlying our system of justice should not be rewarded.

To be fair, however, the modifications Sandoz made to its ANDA following *Allergan I* only tell half of the story underlying this extended litigation. After litigating *Allergan I* before this Court and the Federal Circuit, both parties made moves behind the scenes in anticipation of

future litigation. While Sandoz was amending its ANDA in an effort to relitigate the issues and patents in *Allergan I*, as described above, Allergan was re-writing its claims and prosecuting additional patents to further protect Combigan®. Indeed, one of the patents-in-suit, the '425 patent, is the product of Allergan's efforts to re-write its claim with respect to the fixed combination of brimonidine and timolol. In *Allergan I*, the parties stipulated to the claim construction wherein "brimonidine" was construed as "brimonidine tartrate" and "timolol" was construed as "timolol free base." (C.A. No. 2:09-cv-97, Dkt. No. 151 at 8–12.) After recognizing that this particular construction favored its infringement arguments, Allergan re-wrote the claims of its patents purportedly covering the fixed combination element of Combigan® to identically track the *Allergan I* claim construction. Claim 1 of the '425 patent specifically claims "a single composition comprising 0.2% w/v *brimonidine tartrate* and 0.5% w/v *timolol free base*." '425 Patent at 9:10–11 (emphasis added). Again, the Court observes that this is not improper per se; however, like Sandoz's amended ANDA, it does reflect both parties' realization that they each might be better off if the patents and litigation strategies employed in *Allergan I* were subject to a "do-over." This realization seems to have culminated in the strategic actions that both parties took and which lead to the present suit.

II. ANALYSIS

The Court issues this opinion and sets forth the following analysis in concert with and as an adjunct to its Findings of Fact and Conclusions of Law. The following does not supplement such findings and conclusions, rather they provide an overview of the Court's analysis.

A. Anticipation of the Patents-in-Suit

First, the Court addresses Sandoz's assertion that the patents-in-suit are invalid as anticipated under 35 U.S.C. § 102. In Sandoz's Answer to Allergan's Complaint, it asserted

affirmative defenses and counterclaims of invalidity of the '976 and '425 patents under § 102. (C.A. No. 2:15-cv-347, Dkt. No. 14 at 42–44, 57–58.) Additionally, in Sandoz's First Amended Answer and Counterclaim, it added affirmative defenses and counterclaims of invalidity of the '149 patent under § 102. (Dkt. No. 252 at 41, 54–55.)[1]

Despite the fact that Sandoz's pleadings included affirmative defenses and counterclaims of invalidity of the '140, '976, and '425 patents as anticipated under § 102, it failed to put forth any evidence at trial of a single prior art reference which anticipated any of the patents-in-suit. Accordingly, the Court granted Allergan's motion under Rule 52(c) of the Federal Rules of Civil Procedure for judgment that the patents-in-suit were not invalid as anticipated under § 102.

B. Obviousness of the Patents-in-Suit

Sandoz also asserts that the patents-in-suit are invalid as obvious under 35 U.S.C. § 103. In its Answer to Allergan's Complaint, Sandoz asserted affirmative defenses and counterclaims of invalidity of the '976 and '425 patents under § 103. (C.A. No. 2:15-cv-347, Dkt. No. 14 at 42–44, 57–58.) Additionally, in Sandoz's First Amended Answer and Counterclaim, it added affirmative defenses and counterclaims of invalidity of the '149 patent under § 103. (Dkt. No. 252 at 41, 54–55.)

Under 35 U.S.C. § 103, a claim is invalid if the patented invention would have been obvious in light of the prior art to a person having ordinary skill in the art at the time the invention was disclosed. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415–16 (2007); 35 U.S.C. § 103. A determination of obviousness requires an inquiry into the scope and content of the prior art, the level of ordinary skill in the art, and the differences between the claimed

[1] The Court notes as an initial matter that it previously denied Allergan's motion for summary judgment seeking to preclude Sandoz from arguing the invalidity of claim 4 of the '149 patent. (*See* Dkt. No. 314.) Accordingly, the Court addresses all of Sandoz's substantive arguments on invalidity, including those directed to claim 4 of the '149 patent.

inventions and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). With respect to the obviousness of fixed combination products, "[t]wo ingredients might be therapeutically effective when use[d] separately as part of an overall treatment regimen, yet be incompatible or ineffective when combined in a single solution." *In re Brimonidine*, 643 F.3d 1366, 1374 (Fed. Cir. 2011). Invalidity under § 103 must be proven by clear and convincing evidence. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001). However, where nearly all the prior art cited by the defendant was before the PTO during prosecution, the defendant faces an "enhanced burden." *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011).

1. The '149 and '976 Patents

The Court will address Sandoz's claims of obviousness as to the '149 patent and the '976 patents collectively given the similarity of issues and the fact that both patents were asserted in *Allergan I*. Although the Court held, at the summary judgment stage, that Sandoz was not legally precluded from asserting obviousness, the Court finds that the '149 and '976 patents are not invalid under § 103 for the same reasons set forth in *Allergan I* (which were affirmed as to the '149 patent by the Federal Circuit).

Claim 4 of the '149 claims a method for treating glaucoma or ocular hypertension with a fixed combination of brimonidine and timolol administered twice daily without loss of efficacy as compared to a three times daily administration of brimonidine. '149 patent at 10:10–17. Similarly, the '976 patent covers a method of treating glaucoma or ocular hypertension by administering a therapeutically effective amount of the same fixed combination of brimonidine and timolol. '976 patent at 10:13–19. In *Allergan I*, this Court held that the '149 and '976 patents were not invalid as obvious despite certain prior art references advanced by Sandoz. *Allergan I*, 818 F. Supp. 2d at 1011. On appeal, the Federal Circuit found that the fixed combination of

brimonidine and timolol was obvious, but nevertheless affirmed the Court's ruling with respect to claim 4 of the '149 patent. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1294 (Fed. Cir. 2013). According to the Federal Circuit, Sandoz failed to prove that that the "no loss of efficacy" element of the '149 patent was obvious. *Id.*

The obviousness case presented at trial in the present suit overlaps substantially with the obviousness case presented in *Allergan I*. For example, in *Allergan I* Sandoz asserted that the DeSantis, Timmermans, Sall, Larsson, Goni, Airaksinen, Clineschmidt, Diestelhorst, and Strohmeier references, along with the Alphagan, Timoptic, and Cosopt labels rendered the '149 and '976 patents invalid. *Allergan I*, 818 F. Supp. 2d at 987–89, 1013. As the Court noted in 2011, many of the references Sandoz relied on to prove obviousness were additionally before the Patent and Trademark Office during prosecution. *Id.* at 1013. Similarly, in the present suit Sandoz asserted that the DeSantis (DTX-1051), Timmermans (DTX-1150), Larsson (DTX-1121), Airaksinen (DTX-1331), and Clineschmidt (DTX-1169) references, along with the Alphagan®, Timoptic®, and Cosopt® labels rendered the '149 and '976 patents invalid. (Trial Tr. Day 1 PM at 150:15, 156:22, 171:22–24, 182:3, 182:19, 183:3; Trial Tr. Day 2 AM at 18:4.) Further, in *Allergan I* Sandoz presented Dr. Angelo Tanna as an expert in the field of ophthalmology to support its § 103 arguments. *Allergan I*, 818 F. Supp. 2d at 988. The same Dr. Tanna testified in the present suit on behalf of Sandoz in support of its § 103 arguments. (Trial Tr. Day 1 PM at 139:8.)

In sum, the Court finds that substantially the same arguments and evidence as to obviousness of the methods claimed in the '149 and '976 patents were presented here as in *Allergan I*. In light of this fact, there is no cogent reason to depart from the prior decisions of this Court and the rulings of the Federal Circuit. Although Sandoz was not legally precluded from

advancing the same arguments, as a factual matter Sandoz has not presented any new evidence to satisfy its "enhanced burden" to prove obviousness. The Court finds that the '149 and '976 patents are not invalid as obvious.

2. The '425 Patent

Sandoz additionally argues that the '425 patent is invalid under § 103 as obvious in light of certain prior art references. Unlike the '149 and '976 patents, however, the '425 was not asserted by Allergan in *Allergan I*, and as such the Court has not previously addressed the issue of invalidity of the '425 patent. However, for similar reasons as those set forth above and in *Allergan I* with respect to the '149 and '976 patents, the Court finds that the '425 patent is not invalid under § 103.

The '425 patent claims two primary components: (1) a method of administering the fixed combination of brimonidine and timolol, and (2) the reduced incidences of certain adverse events. It is the second component claimed by the '425 patent on which Sandoz failed to carry its burden to prove obviousness. At trial, Sandoz argued that the reduction of adverse events would be inherent from the use of brimonidine and timolol in one bottle. (Trial Tr. Day 2 AM at 102:13–14). In support of this argument, Sandoz's expert, Dr. Samples, relied on the Goni (DTX-1209), Konstas (DTX-1397), Adkins (PTX-34), Walters (DTX-1110), Dean (DTX-1052), Sherwood (DTX-1111), Craven (DTX-1393), Pisella (DTX-1197), Noecker (DTX-1196), Broadway (DTX-1191), Rosenthal (DTX-1394), Arici (DTX-1125), Yuksel (DTX-1127), and Stewart (DTX-1320) references, along with the Alphagan® and Timoptic® labels. (Trial Tr., Day 2 AM at 103:3–6, 109:13, 111:7–8, 113:8, 117:9–11, 118:16–20, 120:9–11, 124:7, 132:20–22, 134:3–4, 137:19–20; Trial Tr., Day 2 PM at 27:2-12.) Sandoz argues that each of these references essentially stands for the same proposition: when one combines brimonidine with

timolol, the adverse effects of brimonidine do not increase. However, all but two of the prior art references presented by Sandoz are cited on the face of the '425 patent and were considered by the PTO. '425 patent at p. 1–5.

Additionally, during prosecution of the '425 patent, the PTO had the benefit of the Federal Circuit's opinion in *Allergan I* and the analytical framework it provided with respect to the obviousness of claim 4 of the '149 patent. Like the '149 patent, the '425 patent claims a fixed combination of brimonidine and timolol plus an additional limitation. In the '149 patent the additional limitation is the administration twice a day without loss of efficacy; in the '425 patent the additional limitations are the reduction in adverse events. Although the Federal Circuit held that the fixed combination covered in Allergan's patents was obvious in *Allergan I*, it held that Sandoz failed to establish that the efficacy limitation of the '149 patent was obvious. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1294 (Fed. Cir. 2013). Given this ruling and analysis, the focus of the PTO's efforts during prosecution would likely have been on the obviousness of the reduction of adverse events, rather than the fixed combination. With a list of cited references occupying four and a half pages of the '425 patent (many of which were presented as invalidating prior art at trial) and the narrowed focus provided by the Federal Circuit in *Allergan I*, the PTO had ample ammunition with which it could have found the reduction in adverse events obvious. Nevertheless, the '425 patent issued. Therefore, the Court finds that for these reasons, in addition to the reasons further discussed in its Findings of Fact and Conclusions of Law, Sandoz has failed to carry its "enhanced burden" to prove that the reduction in adverse events would have been obvious. Accordingly, the Court finds that the '425 patent is not invalid under § 103.

C. Written Description and Enablement of the Patents-in-Suit

Sandoz also argued (both during summary judgment and at trial) that the patents-in-suit are invalid under 35 U.S.C. § 112 for failing to satisfy the written description and enablement requirements. Specifically, in its Answer to Allergan's Complaint, Sandoz asserted affirmative defenses and counterclaims that the '976 and '425 patents were invalid for failure to comply with § 112. (C.A. No. 2:15-cv-347, Dkt. No. 14 at 42–44, 57–58.) In its First Amended Answer, Sandoz also asserted as affirmative defenses and counterclaims that the '149 patent was invalid for failure to comply with § 112. (C.A. No. Dkt. No. 252 at 41, 54–55.) However, despite pleading that each of the patents-in-suit is invalid under § 112, at trial Sandoz only made § 112 invalidity arguments with respect to claim 4 of the '149 patent. Otherwise, Sandoz abandoned its § 112 position.

Section 112, ¶ 1 provides, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(1). The Federal Circuit has established that this statute sets forth two separate and distinct requirements, known as "written description" and "enablement." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Although distinct requirements, the doctrines of written description and enablement are related and "often rise and fall together." *Id.* at 1352. "The test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* at 1351. A sufficient description of a genus requires the "disclosure of either a representative number of species falling within the scope of the genus or structural features common to the

members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Id.* at 1350. Under Federal Circuit precedent, even a single representative embodiment can support written description of a claimed genus. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125–26 (Fed. Cir. 2004).

Courts have held that the enablement requirement is "more indulgent" than the written description requirement. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003). "The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without undue experimentation." *Id.* Sandoz bears the burden to establish invalidity for failure to meet the written description and enablement requirements of § 112 by clear and convincing evidence. *Id.*; *Invitrogen Corp.*, 429 F.3d at 1072.

Sandoz's primary argument that claim 4 of the '149 patent is invalid under § 112 applies with equal effect to both the written description and enablement requirements. At trial, Dr. Tanna relied on this Court's claim construction in testifying that claim 4 of the '149 was invalid for lack of written description and enablement. (Trial Tr., Day 1 PM at 167:16–20.) Previously, this Court construed the term "brimonidine," as it appears in claim 4 of the '149 patent, "according to its plain and ordinary meaning, the chemical compound brimonidine, including both its free base and salt forms." (Dkt. No. 241 at 17.) Similarly, the Court construed the term "timolol," as it appears in claim 4 of the '149 patent, "according to its plain and ordinary meaning, the chemical compound timolol, including both its free base and salt forms." (*Id.* at 20.) In light of the construction of these terms, Dr. Tanna testified that "the composition can be many, many

different things because there are many different salts of brimonidine and many salts of timolol and their respective free bases as well." (Trial Tr. Day 1 PM at 167:17–20.) According to Dr. Tanna, "there are many different formulations that can be within the scope of this claim and it is unclear whether or not they would meet the efficacy element that's required." (Trial Tr., Day 1 PM at 167:25–168:2.)

However, as set forth more comprehensively in its Findings of Facts and Conclusions of Law, the Court disagrees with Sandoz's characterization of the breadth and number of possible combinations of brimonidine and timolol under claim 4 of the '149 patent. To rebut the testimony of Dr. Tanna, Allergan presented the testimony of Dr. Noecker. Dr. Noecker testified that Example 1 from the '149 patent was identical to the Combigan product produced by Allergan, which in turn is chemically identical to Sandoz's generic product. (Trial Tr., Day 2 PM at 186:9–17.) Therefore, according to Dr. Noecker, the specification properly instructs how to make this particular formulation of brimonidine and timolol. (*Id.*) Additionally, and perhaps most importantly, Allergan and Dr. Noecker established that the "many different formulations of brimonidine and timolol" (that Dr. Tanna testified invalidate the '149 patent) are premised on the existence of purely hypothetical salts. (Trial Tr. Day 2 PM at 189:14–20.) In other words, "in the real world," there are only 6 different combinations of brimonidine and timolol that the '149 patent claims, not hundreds, and a person of ordinary skill in the art would understand this to be the breadth of the claims. (*Id.*) For these reasons, the Court finds that claim 4 of the '149 patent is not invalid for failure to satisfy the written description and enablement requirements of § 112.

D. Infringement

Allergan alleges that Sandoz's amended ANDA No. 91-087 infringes the '149, '976, and '425 patents under 35 U.S.C. § 271(b), (c), and (e)(2). (C.A. No. 2:15-cv-347, Dkt. No. 1 at ¶¶ 41–94, 135–161.)

Section 271(b) provides for liability for induced infringement, and states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Since liability under § 271(b) is premised on "purposeful, culpable expression, and conduct," a showing of mere knowledge of potential infringing uses is not sufficient to establish inducement. *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). In the Hatch-Waxman context, however, a proposed label that instructs users to perform the patented method "may provide evidence of [the ANDA applicant's] affirmative intent to induce infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

Section 271(c) provides for liability for contributory infringement, and states that

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c). As the Supreme Court has observed, "the concept of contributory infringement is merely a species of the broader problem of identifying the circumstances in which it is just to hold one individual accountable for the actions of another." *Sony Corp. of Am. v. Universal Studios, Inc.*, 464 U.S. 417, 435 (1984). Given this "vicarious" nature of

contributory infringement, "[t]here can be no contributory infringement without direct infringement." *Serrano v. Telular Corp.*, 111 F.3d 1578, 1584 (Fed. Cir. 1997).

> Section 271(e)(2) provides for a statutory act of infringement upon the submission of:
>
> > an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). "When a patentee seeks to block FDA approval of an [ANDA] under 35 U.S.C. § 271(e)(2)(A), the infringement inquiry focuses on the hypothetical infringement that would occur if the defendant's [ANDA] were approved and the defendant began to make and sell the drug." *Novartis Corp. v. Ben Venue Laboratories, Inc.*, 271 F.3d 1043, 1047 (Fed. Cir. 2001).

While subsections (b), (c), and (e)(2), provide liability for different forms of infringement, Allergan's infringement arguments in this case generally center around its assertion that Sandoz's generic product meets the fixed combination limitation of each of the patents-in-suit. Unsurprisingly, Sandoz disputes this fact vehemently and devoted much of its infringement arguments at trial to disproving this fact. Accordingly, the Court's discussion of infringement herein will focus on the issue of whether Sandoz's proposed product meets the fixed combination limitation of each patent. A more detailed analysis as to infringement can be found in this Court's Findings of Fact and Conclusion of Law.

With respect to the '149 and '976 patents, the Court finds that Sandoz's proposed product does not meet the limitation contained in both claims that requires a fixed combination of "0.2% brimonidine by weight and 0.5% timolol by weight." For this reason, the Court addresses the infringement of these two patents collectively. However, with respect to the '425 patent, the

Court finds that Sandoz's proposed product does meet its limitation requiring a fixed combination of "0.2% w/v brimonidine tartrate and 0.5% w/v timolol free base."

1. The '149 and '976 Patents

Claim 4 of the '149 patent claims

> A method of reducing the number of daily topical ophthalmic doses of brimonidine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy, wherein the concentration of brimonidine is 0.2% by weight, said method comprising administering said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition.

'149 patent at 10:10–17. Similarly, claim 1 of the '976 patent claims

> A method of treating glaucoma or ocular hypertension which comprises topically administering a therapeutically effective amount of a single composition comprising brimonidine at a concentration of about 0.2% by weight and timolol at a concentration of about 0.5% by weight in a pharmaceutically acceptable carrier thereof, to the affected eye, wherein said composition is administered twice a day.

'976 patent at 10:13–19. Common to both of these claims is the limitation requiring a fixed combination of 0.2% brimonidine by weight and 0.5% timolol by weight.

At trial, Sandoz argued that its proposed product, which is chemically identical to Combigan®, did not meet the fixed combination requirement of the '149 and '976 patents. In other words, Sandoz argued that Allergan's own product did not practice its own patents. (Trial Tr., Day 1 PM at 196:10–11.) As unusual as this argument may be, the Court agrees with Sandoz. The record at trial demonstrates that Combigan® (and, by extension, Sandoz's proposed product) is a fixed composition of 0.2% brimonidine tartrate by weight and 0.68% timolol maleate by weight. (Trial Tr., Day 1 PM at 45:7–15.) When the maleic acid is removed from the 0.68% timolol maleate, the remaining portion of the compound is 0.5% by weight timolol free base. (Trial Tr., Day 1 PM at 87:25–88:15.) Accordingly, the element of the claim requiring the combination to include 0.5% timolol by weight is met. Under this same reasoning, however, the

record establishes that removing the acidic component of 0.2% brimonidine tartrate by weight leaves, at most, 0.132% brimonidine free base. (Trial Tr., Day 1 PM at 87:25–88:15.) Simply put, Combigan® and Sandoz's proposed product feature a fixed combination of 0.5% timolol and 0.132% by weight brimonidine. This combination does not meet the fixed combination limitation of the '149 and '976 patents.

This Court's claim construction, which broadly construed brimonidine and timolol, does not save Allergan. As discussed above, the Court construed "brimonidine" to include "both its free base and salt forms." (Dkt. No. 241 at 17.) Similarly, the Court construed the term "timolol" to include "both its free base and salt forms." (*Id.* at 20.) Despite this fact, Allergan cannot successfully argue that the claim construction permits a "mix and match" approach, wherein the term "brimonidine" refers to "brimonidine tartrate" and the term "timolol" refers to "timolol free base." In other words, any argument that the claims are not so limited as to require 0.2% brimonidine *free base* and 0.5% timolol *free base* must fail. Previously, this Court found that "brimonidine" and "timolol" should be interpreted consistently. Specifically, at claim construction the Court rejected a similar argument when it held that "Allergan had offered no compelling reason why one chemical compound, brimonidine, should be interpreted as limited to a particular brimonidine salt, while another chemical compound, timolol, should be interpreted as 'timolol free base.'" (Dkt. No. 241 at 16.) The Court finds that this same reasoning applies equally following the bench trial in this case.

Perhaps recognizing such, Allergan spent the bulk of its infringement case at trial arguing that Sandoz's proposed product was identical to Combigan®. The Court agrees. However, this fact in isolation does not establish infringement. While Allergan successfully proved that Sandoz's proposed product was identical to Combigan®, it did not establish that Combigan®

met each limitation of its patents. For these reasons, Sandoz's proposed product does not meet the fixed combination limitation of the '149 and '976 patents and therefore does not infringe.

2. The '425 Patent

The above analysis makes the issue of whether the proposed product meets the '425 patent's fixed combination limitation relatively simple. Unlike the '149 and '976 patents, the fixed combination limitation in the '425 does not claim "brimonidine" and "timolol." Rather, the '425 patent specifically claims a fixed combination of "0.2% w/v brimonidine tartrate and 0.5% w/v timolol free base." '425 patent at 9:10–11. As discussed earlier, the record at trial established that Combigan® (and, by extension, Sanodz's proposed product) is a fixed combination of 0.2% brimonidine tartrate and 0.68% timolol maleate. (Trial Tr., Day 1 PM at 45:7–15.) When the maleic acid in the timolol maleate compound is removed, the only remaining component is 0.5% timolol free base. (Trial Tr., Day 1 PM at 88:5–10.) Therefore, Combigan® and Sandoz's proposed product both have a fixed combination of 0.2% brimonidine tartrate and 0.5% timolol free base. (Trial Tr., Day 1 PM at 87:25–88:10.) This combination is precisely what the '425 patent claims. Accordingly, Sandoz's proposed product meets the fixed combination limitation of the '425 patent. Allergan also presented sufficient evidence, in the form of studies and testimony, that Combigan® and Sandoz's proposed product meet the '425 patent's limitation requiring the reduction of adverse events. (*See* PTX-13F; Trial Tr., Day 1 PM at 15:2–5; 63:5–8.) Indeed, Sandoz did not dispute this fact at trial. Accordingly, the Court finds Sandoz proposed product infringes the '425 patent.

III. FINAL JUDGMENT

For the reasons stated herein and further developed in the Court's Findings of Facts and Conclusions of Law, the Court enters judgment as follows:

1. Allergan asserted the following claims against Sandoz: claim 4 of the ’149 Patent, claim 1 of the ’976 Patent, and claims 1–8 of the ’425 Patent;
2. The product described in Sandoz’s amended Abbreviated New Drug Application No. 91-087 does not infringe claim 4 of the ’149 Patent;
3. The product described in Sandoz’s amended Abbreviated New Drug Application No. 91-087 does not infringe claim 1 of the ’976 Patent;
4. The product described in Sandoz’s amended Abbreviated New Drug Application No. 91-087 does infringe claims 1–8 of the ’425 Patent;
5. The product described in Sandoz’s amended Abbreviated New Drug Application No. 91-087 would induce and contribute to the infringement of claims 1–8 of the ’425 Patent;
6. The asserted claims are not invalid for anticipation;
7. The asserted claims are not invalid for obviousness; and
8. The asserted claims are not invalid for failure to satisfy the written description and enablement requirements;
9. The effective date of any approval of Sandoz’s amended Abbreviated New Drug Application No. 91-087 under § 505(j) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. § 355(j)) for the drug products described therein shall be a date not earlier than the expiration date of the ’425 patent, plus any exclusivities afforded under the statute;
10. Sandoz, its officers, agents, servants, employees, attorneys, and other persons in active concert or participation therewith, are enjoined from making, using, offering to sell, or selling the products described in Sandoz’s amended Abbreviated New Drug Application No. 91-087 within the United States or importing the described products into the United

States until after the expiration date of the '425 patent, plus any exclusivities afforded under the statute;

11. The injunction issued as part of the Court's judgment in *Allergan I* remains in full force and effect and is in no manner limited or disturbed by this judgment.

This is a **FINAL JUDGMENT.** All motions not previously ruled on are **DENIED**. The Clerk shall close this case.

So ORDERED and SIGNED this 30th day of December, 2016.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE